

**REMARKS**

By the present communication, claims 1, 2, 5, 12-15, 17 and 22 are currently amended. No new matter is introduced as support for the amended language may be found throughout the application as filed, including but not limited to page 5, lines 21-22 and the original claims. Applicant notes that, contrary to page 1 of the present Office Action, claims 20 and 21 were canceled in a preliminary amendment and are not pending. Rather, claims 1-19 and 22 remain pending.

In the Action dated April 8, 2010, the Office imposed a restriction among the claims as allegedly lacking unity of invention because they lack the same or corresponding special technical features. In support thereof, the Office cited WO 00/25746 as allegedly describing the claimed micronization process. The Office now requires Applicant to elect one group of claims for further prosecution from among the following three groups:

Group I – claims 1-18, directed to a process of micronization

Group II – claim 19, directed to the process of claim 1 wherein said micronized  
pharmaceutically active agent is prepared in situ in an inhalation device

Group III – claim 22, directed to an apparatus for micronization

Applicant hereby elects Group I, claims 1-18, with traverse.

Unity of invention exists when the claimed inventions involve one or more of the same or corresponding special technical features. PCT Rule 13.2; 37 C.F.R. 1.475(a); see also MPEP 1850, II. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. *Id.* Moreover, unity of invention is to be considered in the first place only in relation to independent claims and not dependent claims. MPEP 1850, II., paragraph 6. If an independent claim avoids the prior art and satisfies the requirement of unity of invention, so do any claims which depend from the independent claim. *Id.*, paragraph 7. Finally, under 37 CFR 1.475(b)(4), a national stage application containing claims to different categories of inventions will be

considered to have unity of invention if the claims are drawn to a process and an apparatus or means specifically designed to carry out that process.

As amended, claims 1-19 and 22 meet the unity of invention standard as set forth above. First, claim 19 depends from independent claim 1 and must include common subject matter with claim 1. In accordance with the unity of invention standard, if claim 1 has unity of invention, then its dependent claims, including claim 19, have unity of invention. Applicant submits that claim 1 has unity of invention for the following reasons.

Claim 1 satisfies the unity of invention standard because it is novel and inventive over WO 00/25746. Claim 1 recites a micronization process that includes the step of suspending the pharmaceutically active agent in a gas propellant or in a compressed gas. The claimed micronization processes offers improved control of micron and submicron particle size and distribution, results in fewer post processing steps, and avoids problems associated with high volumes of solvent and less mild micronization conditions. Application, p. 2, lines 3-7; p. 10, lines 14-21. Applicant respectfully submits that the suspension step is part of the special technical features that the invention, considered as a whole makes over the art. WO 00/25746 does not teach or suggest the use of a gas propellant or compressed gas for suspension of the active ingredient in a micronization process. In fact, the cited reference teaches that the active ingredient is suspended in a liquid (aqueous) solution, not a gas (p. 2, lines 31-32). Thus, because claim 1 and its dependent claims, including claim 19, share the same special technical features, they have unity of invention.

Second, because claim 22 describes an apparatus specifically designed for carrying out the process of claim 1, it also has unity of invention with claim 1. Pages 7 and 8 of the application describe the apparatus of claim 22 and its use in carrying out the processes of claim 1. Therefore, claim 22 is specifically designed to carry out the processes of claim 1 and has unity of invention with claim 1 in accordance with 37 CFR 1.475(b)(4).

For the reasons above, Applicant therefore respectfully requests withdrawal of the restriction requirement and rejoinder of all claims for examination.

Applicant believes that the present application is in condition for allowance. Favorable consideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date: May 5, 2010

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